UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,320	06/12/2001	Ajay Hasmukhlal Upadhyay	RD 01022	5176

7590 07/26/2007

Rhodia Inc.
CN 7500
8 CEDAR BROOK DRIVE
Cranbury, NJ 08512

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/879,320	UPADHYAY, AJAY HASMUKHLAL	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,31 and 33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,31 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response dated 1-18-07 and amendment and response dated 4-13-07 is acknowledged.

Claims 1-4, 6-8,.31 and 33-36 are pending in the instant application.

Response to Arguments

Applicant's arguments filed 1-18-07 and 4-13-07 have been fully considered but they are not persuasive.

Examiner herewith clarifies that claims 5 and 32 have been canceled and that the rejection of record (dated 8-23-06) is pertinent to claims 1-4, 6-8, 31 and 33-36 only.

The following rejection has been applied in the last office action:

Claim Rejections - 35 USC § 103

Claims 1-8 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,372,252 to Blume et al (Blume) in view of US 5,032,406 to Dansereau et al (Dansereau).

Blume teaches immediate and sustained release formulations comprising guaifenesin. Blume teaches loading guaifenesin and methocel into a high shear mixer, mixed at high speed, adding water and further mixing at additional time to complete granulation. The composition is next dried in fluid dryer and then passed through a mill fitted a suitable size screen (col. 7, lines 63 through col. 8, lines 23). Thus, the resulting material of Blume reads on agglomerated mixture because the processing of the material involves the same steps as described in the instant application.

Blume fails to teach granulation of guaifenesin with polyvinylpyrrolidone.

Dansereau teaches a tablet composition that provides dual action, for immediate and sustained release, comprising an outer tablet and an inner tablet respectively. The active ingredient of both inner and outer tablets comprises guaifenesin. The inner tablet particularly comprises guaifenesin and polyvinylpyrrolidone (PVP) (example I). Dansereau teaches that the inner tablet is made as follows (col. 6):

> The inner tablet is made by oscillating guaifenesin and half of the polyvinylpyrrolidone through a 30 mesh screen. The blend is then transferred to a pharmaceutical grade blender and mixed until it is of uniform consistency. It is then granulated with polyvinylpyrrolidone that had been previously dissolved in a sufficient amount of purified water to make a solution of from about 8% to about 12% of polyvinylpyrrolidone. This mixture is discharged and dried in a forced air oven at 40° C. until the water content is less than 1%. The dried granulation is then oscillated through a 12 mesh screen and returned to the blender. The remaining polyvinylpyrrolidone, microcrystalline cellulose and talc are added to this dried granulation and mixed until it is of uniform consistency. Finally, zinc stearate is added and the mixture is mixed until it is of uniform consistency. This mixture is then compressed into inner tablets using a standard tableting press.

Thus, the resulting inner tablet composition of Dansereau read on the claimed agglomerate mixture because the process involves the same steps as described in the instant specification (page 3, lines 15-20).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ PVP or methocel for the processing and preparation of

compressible guaifenesin tablets because Dansereau recognizes methylcellulose (Blume) and PVP as both binders as well as disintegrants and the prior art references (Blume and Dansereau) recognize both the excipients as suitable for preparing a sustained release compressible tablet preparation comprising guaifenesin.

For the claimed additives such as glidants, lubricants, silica, stearic acid etc., Blume and Dansereau teach the conventional excipients including lubricants such as magnesium stearate, calcium stearate etc; binders such as povidone (polyvinylpyrrolidone), gelatin, starch; glidants such as talc or silicon dioxide, stabilizers and other excipients such as lactose, sorbitol etc. Accordingly, in the absence of evidence to the criticality of the specific excipients and their amounts (claims 3-4 & 33-34), it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to the choose the appropriate excipient and optimize the amounts of the same in the composition of Blume with an expectation to achieve the desired effect.

With respect to the claimed particle sizes, Blume teaches that no more than 30% granulation material passes through 100 mesh (150 microns) and not more than 10% retained on 10-mesh screen (greater than 850 microns). Thus, majority of the particles of Blume are in the range of 150 microns – 2 mm and a smaller percentage of particles are below 150 microns. A maximum of 30% of the particles that pass through the 100-mesh screen, according to Blume, could be any size below 150 microns (as low as 45 microns claimed in the instant invention). While Blume does not teach the exact percentages of particle sizes claimed in the instant application, in the absence of any

unexpected results obtained with the claimed particle sizes and in particular, the percentages of particles, optimizing the sizes of the particles and the percentages of the particles of an agglomerated mixture of guaifenesin and methocel would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made because Blume suggests a sustained release of the guaifenesin with the above process of preparation.

RESPONSE: applicants argue that Blume does not satisfy the limitations of claim 1 because Blume fails to teach the agglomerate of guaifenesin and PVP and the particle size distribution. It is argued that Blume as well as Dansereau do not teach the instant process of preparing the composition. It is further argued that Dansereau broadly teaches that 100% particles are less than 1680 microns and does not teach the claimed size of guaifenesin and PVP. It is argued that a skilled artisan would not have found that the present invention obvious because Blume lacks claimed particle sizes and Dansereau fails to remedy this deficiency. While acknowledging the examiner analysis of the claimed particle sizes, it is argued that Blume does not teach exact particle sizes and instead that 60% to 100% of Blume's particles are between 150-2000 microns, which is a very broad range. It is argued that the prior art fails to recognize the problems addressed by Applicant's invention, i.e., the sensitivity of guaifenesin compositions to processing conditions and difficulty in making satisfactory compressed guaifenesin dosage forms and the tendency of guaifenesin compositions to exhibit inadequate flow properties and to slow production of compressed guaifenesin dosage forms and of the need for guaifenesin compositions that offer both improved flow properties and

improved robustness with regard to compression processing conditions (see p. 1, line 28 to p. 2 line 25 of the present application), and lacking any recognition of such problems.

Applicants' arguments are not persuasive because instant claims are directed to a composition and not a process step. Blume teaches the granulated composition comprising particulate guaifenesin for obtaining sustained release of guaifenesin and the desired bioavailability. Blume and Dansereau teach the composition with excipients that are conventionally used in tabletting i.e., binders, lubricants etc.; While Blume fails to teach PVP Dansereau teaches PVP as equivalent to methocel (employed by Blume). Instant rejection cites Dansereau for the addition of PVP and not particle sizes. Accordingly, the argument that the reference fails to teach claimed particle size is not persuasive. With respect to the particle size, it is admitted that Blume does recognize particle sizes though not exactly the same size as claimed. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382. In this regard, applicants have not shown any unexpected advantage in the

selection of the above particle sizes and therefore the mere argument that the exact sizes are not taught by prior art is not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
July 21, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER